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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/026,400	02/19/98	MORI S	2185-0226P-S

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EXAMINER	
NELSON, A	
ART UNIT	PAPER NUMBER
1638	18

DATE MAILED: 05/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/026,400	Applicant(s) MORI ET AL.	
	Examiner Amy Nelson	Art Unit 1638	

-- The MAILING DATE of this communication appears n the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11 and 13-20* is/are pending in the application.

4a) Of the above claim(s) *14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☒ Other: *Notice to Comply with Requirements...* .

DETAILED ACTION

1. The finality of the last Official action mailed 7/6/00 has been withdrawn in view of the following new grounds of rejection.

2. The amendment filed 1/8/01 has been entered.

Sequence Rules

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Specifically, there is a lack of agreement between the paper copy (in which SEQ ID NO:1 and 2 are amino acid sequences and SEQ ID NO:3 and 4 are nucleic acid sequences) and the computer readable form (in which SEQ ID NO:2 and 4 are amino acid sequences and SEQ ID NO:1 and 3 are nucleic acid sequences). Also, the paper copy contains 5 sequences, whereas the CRF contains 7 sequences. Appropriate amendment to the specification is required.

Full compliance with the Sequence Rules is required in response to this Official action. A complete response to this Official action should include both compliance with the Sequence Rules and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Official action will be held to be non-responsive.

Election/Restriction

4. This application contains claims 14-20 drawn to an invention nonelected with traverse in Paper No. 10, filed 7/26/99. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 2, and 5-11, and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn broadly toward a gene encoding nicotianamine aminotransferase, as well as transformants comprising said gene, and transformation methods with said gene. Applicant describes two cDNA sequences from barley encoding nicotianamine aminotransferase (SEQ ID NO:3 and 4). Applicant does not describe the composition or structure of a gene encoding nicotianamine aminotransferase or other DNA sequences encoding nicotianamine aminotransferase, and hence it is not clear from the instant specification that the Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

8. Claims 2, and 5-11, 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to a DNA encoding the nicotianamine aminotransferase of SEQ ID NO:1 and 2, vectors, transformed plant and bacterial cells, and transgenic plants comprising said DNA, as well as a method of enhancing iron absorbing ability of a plant cell with said DNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The scope of enablement has been modified to include methods of enhancing iron absorbing ability of a plant cell with a DNA encoding the nicotianamine aminotransferase of SEQ ID NO:1 or SEQ ID NO:2, in view of Applicant's arguments in the response filed 1/8/01.

The claims are indefinite for the reasons disclosed below. In particular, the claimed hybridization conditions are indefinite and hence the claims read on any DNA encoding nicotianamine aminotransferase. Further, Claim 11 encompasses any plant DNA encoding nicotianamine aminotransferase. Applicant also claims expression plasmids and transformants comprising said DNA, as well as a process for enhancing iron absorbing ability of a plant cell by transformation with said DNA.

Applicant teaches protein isolation from triturated root of barley treated for iron deficieny, dialysis with pfAPMSF, fractionation and separation on a nicotianamine column, and N-terminal sequencing of an identified nicotianamine aminotransferase protein (Example 1). Applicant also teaches PCR amplification based on the protein sequence and identification of a 600 bp PCR product, as well as screening of a cDNA library prepared from barley root treated for iron deficiency (Examples 3-4). Applicant teaches sequencing of two isolated clones (Example 5; SEQ ID NO:3 and 4, encode SEQ ID NO:1 and 2). Applicant does not teach other isolated DNAs encoding nicotianamine aminotransferase other than the disclosed sequences, Applicant does not teach transformants other than transformed bacteria or plants, and Applicant does not teach a method of enhancing iron absorbing ability of a plant cell.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The state of the art for isolation of cDNA or genomic clones with a defined functionality is highly unpredictable. Significant guidance is required with regard to hybridization/wash conditions and/or PCR conditions that will allow specific isolation of the target genes. Applicant has characterized and isolated two cDNAs (SEQ ID NO:3 and SEQ ID NO:4) from barley encoding nicotianamine aminotransferase. Applicant has provided no guidance with respect to what hybridization/wash conditions or what PCR reaction conditions would allow specific isolation of additional functionally related DNAs. In the absence of such guidance, undue trial and error experimentation would be required to screen through the vast number of cDNA and genomic clones from barley or another organism, to identify those that are functionally related to SEQ ID NO:3 or SEQ ID NO:4 and also encode nicotianamine aminotransferase. Further, it is noted that whereas Applicant has isolated two cDNAs, Applicant has not isolated a gene, comprising a promoter region. Hence, Applicant is not enabled for a gene *per se*.

Re: Claim 8. The claim encompasses any transformant, including a transformed mammal. Applicant has clearly not provided sufficient guidance to enable transformed mammals. The claims should be limited in scope to a transformed microorganism or a transformed plant.

When the *Wands* factors are weighed it is concluded that undue experimentation would be required to practice the invention throughout the full scope of the claims, and therefore the invention is not enabled.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 2-11, 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 2, lines 5-7, the claimed hybridization conditions without defined wash conditions are indefinite, because the metes and bounds of the claimed invention are unclear. Appropriate correction is required.

At Claim 6, lines 2 and 4, the phrase "capable of functioning" is indefinite because it is unclear whether or not it functions. It is recommended that the phrase be changed to --that functions--.

At Claim 6, line 5, after "operably" it is suggested that --linked-- be inserted for clarity.

At Claim 7, lines 3 and 5, the phrase "capable of functioning" is indefinite because it is unclear whether or not it functions. It is recommended that the phrase be changed to --that functions--.

At Claim 8, line 1, the term "harboring" is indefinite and should be changed to --transformed with-- or --comprising--.

At Claim 9, "the host" lacks proper antecedent basis.

Claim 11 is indefinite because it comprises two method steps "introducing" and "transforming" which are the same. One of the method steps should be deleted.

At Claim 11, lines 2-3 and 4-5, the phrase "iron making use of mugineic acid compound" is indefinite. It is not known what is intended by the phrase. Clarification is required.

At Claim 11, lines 6 and 8, the phrase "capable of functioning" is indefinite because it is unclear whether or not it functions. It is recommended that the phrase be changed to --that functions--.

At Claim 11, line 7, the phrase "plant derived" is indefinite. There are many different types of derivatives and hence it is not known what is encompassed by the phrase. It is recommended that the phrase be changed to --plant--.

At Claim 11, line 9, after "operably" it is suggested that --linked-- be inserted for clarity.

At Claim 13, "the" should be capatilized.

Claim 13 appears to be dependent on a prior claim, but no claim is recited. Appropriate correction is required.

At Claim 13, line 2, "the gene of the nicotianamine aminotransferase" lacks proper antecedent basis.

At Claim 13, lines 7-9, the claimed hybridization conditions without defined wash conditions are indefinite, because the metes and bounds of the claimed invention are unclear. Appropriate correction is required.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 2-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are directed to a gene which is a product of nature, and not one of the five statutory classes of patentable subject matter. Amendment of the claim to recite --isolated-- would obviate this rejection.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Yolanda Vines, whose telephone number is (703) 305-2365.

AMY J. NELSON, PH.D
PRIMARY EXAMINER

Amy J. Nelson, Ph.D.
May 9, 2001

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